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10/598,396	08/25/2006	Erika Hoffmann	JCLA21561	3602

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EXAMINER	
HEYER, DENNIS	
ART UNIT	PAPER NUMBER
1615	
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05/11/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,396	HOFFMANN, ERIKA	
	Examiner	Art Unit	
	DENNIS HEYER	4121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-49, 56-60, 65-70* is/are pending in the application.

4a) Of the above claim(s) *37, 42-44, 56 -60 and 65-70* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-36, 38-41 and 45-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :10/24/2007, 06/11/2008, 05/21/2008.

DETAILED ACTION

Status of Claims

Claims 32 – 70 are currently pending

Election/Restrictions

Applicant's election of Group I, Claims 32 – 49, 56 – 60 and 65 – 70 in the reply filed on April 3, 2009 is acknowledged. Cancellation of Claims 50 – 55 and 61 – 64 is acknowledged. Species election a), b) and c) was made in the reply filed on April 3, 2009. The following species were elected:

a) Linseed oil which reads on Claims 32 – 36 and 38;

b) Palmitic acid, which reads on Claims 40 and 41;

c) Paclitaxel, which reads on Claims 45 – 48;

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 37 and 42 – 44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species, there being no allowable generic or linking claim.

Claims 32 – 36, 38 – 41, 45 – 49 are under examination in the instant office action.

Priority

This application, 10/598,396, filed August 25, 2006 is a national stage entry of PCT/DE05/00327, International Filing Date: February 27, 2005. This application claims the benefit of priority to provisional application 60/551,761, filed: March 11, 2004. This application claims foreign priority under U.S.C. § 119 of German patent application 102004009850.6, filed February 28, 2004. Claims 32 – 36, 38 – 41, 45 – 49 of the instant application are supported in the specification of the provisional application.

Abstract Objection

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because of the use of the legal phrases “said polymer layer” (line 6), “said substances” (line 11) and “to the use of the same” (line 13). In addition, the phrase “containing least one” should be corrected to “containing **at** least one”.

Correction of all improper legal phrases and typographical errors is required. See MPEP § 608.01(b).

Claim rejections – 35 USC § 112 – 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 40 and 45 recites the limitation "the substances not participating in the polymerization" in the composition of Claim 32. There is insufficient antecedent basis for this limitation in these claims. The term “not participating” has not been defined and thus Claims 40 and 45 as well as Claims 41 and 46 – 48, which depend from Claims 40 and 45 respectively, are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Note that it appears that applicant’s intention was to have elected species b) palmitic acid and, c) paclitaxel, as the substances not participating in the polymerization reaction (Claims 40 – 44 and 45 – 48, respectively). If this was, in fact, Applicant's

intention, applicant would be remedial to amend Claim 32 to provide proper antecedent basis.

Claims 56 – 60 and 65 – 70 are incomplete as they are drawn to Claims that have been cancelled. Claims 56 and 57 are dependent from cancelled Claims 50 and 51. Claim 58 is incomplete as it is dependent from cancelled Claim 1. Similarly, Claims 59, 60 and 65 – 70 are incomplete as being dependent from cancelled Claims. Note that although these Claims were initially included within elected Group I, cancellation of Claims 50 – 55 and 61 – 64 from which they depend make it unclear as to their scope with respect to the prior art.

Claim rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Instant Claims 32 – 36, 38 – 39 and 45 – 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Allen-Petit *et al.* in WO 2003/039612, publication date: May 15, 2003 as evidenced by Mallegol et al in Progress in Organic Coatings, 39 (2000), 107 – 113.

Regarding instant Claims 32 – 38, the Allen-Petit reference teaches medical products (Abstract, "intraluminal prosthesis, shunt, catheter or local drug delivery device") comprising Applicant elected specie a) Linseed oil, as the substance that participates in the polymerization (Claim 11, "a device characterized in that said oil or fat comprises an either or not chemically modified", "in particular fish oil, sunflower oil, linseed oil"). Regarding the weight limitation of the substance, linseed oil, that participates in the polymerization reaction (Claims 32 and 39); the reference teaches a device in which the fat or oil coating comprises at least 70 % by weight (Claim 12).

It is noted that the reference does not explicitly teach that linseed oil 'polymerizes', however, the method taught by Allen-Petit in applying the disclosed fats and oils to a stent (including linseed oil) (pages 9, lines 18 - 29 and page 10, lines 1 - 9), which include air drying the prosthesis following applying the oil/solvent emulsion, optionally, more than once, would necessarily result in at least a partial polymerization of linseed oil. As evidence by Mallegol, who teaches that polyunsaturated fatty acids such as linseed oil readily oxidize to form a three dimensional network through a radical process that effects cross-linking of the ethylenic moieties (page 107, Introduction, see also Scheme 3, page 108). Thus, the method taught by Allen-Petit exploits an inherent property of linseed oil, resulting in the coating of a linseed oil-derived polymer coated medical product.

Regarding instant Claims 45 - 47, in which the medical device of instant Claim 32 comprises a substance that does not participate in the polymerization. It is noted that these Claims were rejected under 112 2nd paragraph above as lacking sufficient

antecedent basis. It was also noted that it appeared that applicant intended that this substance be elected specie c) paclitaxel. Accordingly, instant Claims 45 – 48 are examined with respect to specie b) paclitaxel.

As noted above, the Allen-Petit reference taught a medical device that anticipated the medical device within the limitations of instant Claims 32 – 38. The reference also teaches said medical device which further comprises Applicant-elected specie c) paclitaxel (Claim 21, page 6, line 5 – 7).

Regarding the limitation of instant Claim 47, the reference teaches that the therapeutic agent, paclitaxel, may be bound adhesively in the polymer layer (page 2, lines 9 – 11. "the matrix which comprises the therapeutic agent is formed by the biocompatible oil or fat").

Claim rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 48 is rejected under 35 U.S.C.103(a) as being unpatentable over Allen-Petit *et al.* in WO 2003/039612, publication date: May 15, 2003 as evidenced by Mallegol et al in Progress in Organic Coatings, 39 (2000), 107 – 113 in view of Allen-Petit *et al.* in WO 2003/039612, publication date: May 15, 2003.

.As noted in the 102(b) rejection above, the Allen-Petit reference teaches a medical device comprising Applicant elected species a) and c), linseed oil and paclitaxel, respectively, that anticipated the limitations of instant Claims 32 – 36, 38 – 39 and 45 – 47.

Regarding instant Claim 48, drawn to the concentration of active agent on the surface of the medical product, Allen-Petit teaches a medical device comprising Applicant elected species a), linseed oil, and a therapeutic agent. As noted in the 102(b) rejection of instant Claims 45 – 47, the therapeutic agent may be paclitaxel, however Allen-Petit does not teach a concentration of paclitaxel on the surface of the medical device. Allen-Petit does teach a pharmaceutically active concentration of the therapeutic agent tacrolimus of 800 µg deposited onto a 4.8 cm^2 eicosapentaenoic acid coated stent (page 20, line 20). This provides a concentration of active agent equal to 0.16 mg/cm^2, (within the range cited in instant Claim 48). The limitation that the concentration taught by Allen-Petit be pharmaceutically active was demonstrated by a

>20% reduction in in-stent neointimal hyperplasia (page 20, lines 23 – 29). Thus it would have been *prima facie* obvious, to one of ordinary skill in the art, at the time the invention was made, to use the concentration provided by the teachings of Allen-Petit when substituting one therapeutic agent (tacrolimus) for another (paclitaxel).

Claims 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen-Petit *et al.* in WO 2003/039612, as evidence by Mallegol et al in Progress in Organic Coatings, 39 (2000), 107 – 113, as applied to claims 32 – 36, 38 – 39 and 45 – 48 above, and further in view of Kashiwagi et al. in US patent 5,336,698; published: August 9, 1994.

The Allen-Petit reference, as noted in the 102(b) rejection above, teaches a medical device comprising Applicant elected species a) and c), linseed oil and paclitaxel, respectively, that anticipated the limitations of instant Claims 32 – 34, 38 – 39 and 46 – 47. The Allen-Petit reference also teaches the pharmaceutically active concentration range cited in instant Claim 48 for an active agent (103 rejection above).

Regarding instant Claims 40 – 41, drawn to substances not participating in the polymerization reaction cited in instant Claim 32, it is noted that these Claims were rejected under 112 2nd paragraph above as lacking sufficient antecedent basis. It was also noted that it appeared that applicant intended that this substance be elected specie b) palmitinic acid Accordingly, instant Claims 40 and 41 are examined with respect to the prior art, as specie b), palmitinic acid. It is noted that palmitinic acid is commonly referred to as palmitic acid and that the latter name will be used forthwith as it is the name used in the cited prior art references.

Regarding instant Claims 40 and 41, Allen-Petit teaches that the oils or fats may also contain free fatty acids but does not teach that said free fatty acid is Applicant - elected specie palmitic acid. Kashiwagi teaches incorporation of palmitic acid as a ligand for a medical material and notes the superior blood compatibility of fatty acids, including the saturated fatty acid palmitic acid (column 2, lines 45 – 57). Kashiwagi also teaches that bonding of a fatty acid to a medical material may reduce or prevent undesirable physiological properties such as blood clotting, activation of the complement system and platelet adhesion (Abstract). Thus the motivation to combine palmitic acid with the medical product of instant Claim 32 is provided by Kashiwagi. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made, to incorporate the guidance from the teachings of Kashiwagi and add palmitic acid, a known blood biocompatible fatty acid, to a medical product designed to be in intimate contact with blood vessels for the purpose of reducing undesired physiological properties.

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Allen-Petit *et al.* in WO 2003/039612, Mallegol *et al.* in Progress in Organic Coatings, 39 (2000), 107 – 113 and Kashiwagi et al. in US patent 5,336,698; published: August 9, 1994. ,as applied to claims 32 – 36, 38 – 41 and 45 – 48 above, and further in view of Smeds *et al.* in the Journal of Biomedical Materials Research, 54, 114 – 121 (2001).

The Allen-Petit reference, as noted in the 102(b) and 103(a) rejections above, teaches a medical device comprising Applicant elected species a) and c), linseed oil and paclitaxel, respectively, that anticipated the limitations of instant Claims 32 – 34, 38

– 39 and 46 – 47. The reference also teaches the pharmaceutically active concentration range cited in instant Claim 48 for an active agent. Kashiwagi teaches the limitation of Claims 40 – 41, the medical device of instant Claim 32 comprising Applicant-elected specie c), palmitic acid, as the substance not participating in the polymerization reaction.

Neither the Allen-Petit nor the Kashiwagi reference teach the limitation of instant Claim 49, which is drawn to a polymerization catalyst in a biocompatible concentration. Smeds teaches polymerization of acrylate-modified hyaluronic acid polymers which may be cross-linked through ethylenic linkages to produce hydrogels using the photoinitiator catalyst system Eosin Y and triethanolamine (page 117, scheme 1). The reference teaches specific concentrations of catalyst (page 116,, bottom left column, Hydrogel Synthesis). The reference teaches that the hydrogel coatings are used in the biomedical field as device coatings (page 114, Introduction) and that, the catalyst system has been shown to be non-toxic to cells (page 117, right column, 2nd paragraph). Thus, based on the teachings of Smeds, one would have been provided ample guidance to select an appropriate biocompatible polymerization catalyst at a disclosed biocompatible concentration. Thus it would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made, to use the guidance of Smeds who prepared a coating for a medical device using a biocompatible catalyst system at an appropriate, biocompatible concentration, to polymerize the system of instant Claim 32 for the expressed purpose of preparing a polymer coating for a medical device.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS HEYER whose telephone number is (571)270-7677. The examiner can normally be reached on Monday-Thursday 8AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached at (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DH

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615